

DOCKET NO: C1039.70077US00

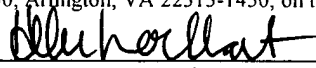
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Arthur M. Krieg, et al.
Serial No: 10/619,279
Confirmation No: 8248
Filed: July 14, 2003
For: IMMUNOSTIMULATORY NUCLEIC ACID MOLECULES

Examiner: Not yet assigned
Art Unit: 1632

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, P.O. Box 1450, Arlington, VA 22313-1450, on the 6 day of January, 2004.


Helen C. Lockhart

Commissioner for Patents
P.O. Box 1450
Arlington, VA 22313-1450

TRANSMITTAL

Sir:

Transmitted herewith are the following documents:

- [X] Supplemental Information Disclosure Statement;
- [X] PTO Form 1449 (copies of references cited);
- [X] Return Receipt Postcard.

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 720-3500, Boston, Massachusetts.

No fee is enclosed. If there is a fee associated with this filing, then please charge the amount to the account of the undersigned, Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

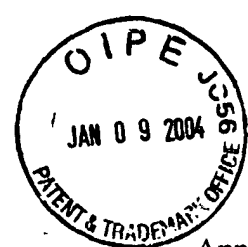
Respectfully submitted,



Helen C. Lockhart, Reg. No. 39,248
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
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Docket No. C1039.70077US00
Date: January 6, 2004
xNDDx





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Helen C. Lockhart, Ph.D., Reg. No. 39,248

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**SUPPLEMENTAL STATEMENT FILED PURSUANT TO THE DUTY OF
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed before the mailing date of a first Office Action on the merits in the above-identified case.

No fee or certification is required.

Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.





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The applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application (copies enclosed):

Docket Number	Serial Number	Filing Date	Inventor(s)
C1037.70013US00	09/776,479	2/2/01	Bratzler et al.
C1037.70016US00	09/009,634	1/20/98	Hutcherson et al.
C1037.70019US00	09/920,313	8/1/01	Bratzler et al.
C1037.70021US00	09/949,194	9/7/01	Peterson et al.
C1037.70025US00	10/017,995	12/14/01	Bratzler
C1037.70038US01	10/735,592	12/11/03	Krieg et al.
C1037.70041US00	10/613,749	7/3/03	Krieg
C1037.70042US00	10/613,524	7/3/03	Krieg
C1037.70043US00	10/613,739	7/3/03	Krieg
C1037.70044US00	10/613,716	7/3/03	Krieg
C1037.70045US00	10/613,228	7/3/03	Krieg
C1037.70046US00	10/445,247	6/5/03	Krieg
C1037.70048US00	10/644,052	8/19/03	Krieg et al.
C1037.70049US00	10/643,141	8/18/03	Hutcherson et al.
C1037.70051US00	10/666,733	9/19/03	Bratzler et al.
C1037.70052US00	10/668,050	9/22/03	Bratzler et al.
C1039.70020US00	09/337,584	6/21/99	Krieg et al.
C1039.70021US01	10/719,493	11/21/03	Krieg et al.
C1039.70022US00	09/337,893	6/21/99	Krieg
C1039.70035US00	09/669,187	09/25/00	Krieg et al.
C1039.70036US00	09/559,140	4/27/00	Noll et al.
C1039.70041US00	09/655,319	9/5/00	Krieg et al.
C1039.70042US00	09/630,319	7/31/00	Krieg et al.
C1039.70043US00	09/629,477	7/31/00	Krieg et al.
C1039.70044US00	09/672,126	9/27/00	Hartmann et al.
C1039.70048US00	09/818,918	3/27/01	Krieg et al.
C1039.70049US00	09/824,468	04/02/01	Krieg et al.
C1039.70052US00	09/888,326	6/22/01	Weiner et al.
C1039.70057US00	09/965,101	9/26/01	Davis et al.
C1039.70058US00	10/023,909	12/18/01	Davis et al.
C1039.70060US00	10/112,653	3/29/02	Krieg et al.
C1039.70061US00	10/161,229	6/3/02	Krieg et al.





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Docket Number	Serial Number	Filing Date	Inventor(s)
C1039.70062US00	10/187,489	7/2/02	Krieg et al.
C1039.70063US00	10/224,523	8/19/02	Krieg et al.
C1039.70065US00	10/272,502	10/15/02	Krieg et al.
C1039.70067US00	10/300,247	11/20/02	Davis et al.
C1039.70068US00	10/306,522	11/27/02	Krieg et al.
C1039.70069US00	10/314,578	12/9/02	Krieg et al.
C1039.70070US00	10/382,822	3/6/03	Krieg et al.
C1039.70071US00	10/435,656	5/9/03	Krieg et al.
C1039.70072US00	10/434,696	5/9/03	Davis et al.
C1039.70073US00	TBD	12/22/03	Krieg et al.
C1039.70075US00	10/613,916	7/3/03	Krieg et al.
C1039.70078US00	10/627,331	7/25/03	Krieg et al.
C1039.70079US00	10/627,413	7/25/03	Krieg et al.
C1039.70082US00	10/631,676	7/30/03	Krieg et al.
C1039.70083US00	10/690,495	10/21/03	Krieg
C1039.70084US00	10/649,584	8/25/03	Krieg et al.
C1040.70006US00	09/316,199	5/21/99	McCluskie et al.
C1040.70010US00	09/768,012	1/22/01	Davis et al.
C1041.70002US00	09/241,653	2/2/99	Wagner et al.
C1041.70005US00	09/355,254	7/23/99	Wagner et al.
C1041.70010US00	09/786,436	9/3/99	Wagner et al.
C1041.70014US00	09/895,007	6/28/01	Schetter et al.
C1041.70016US00	09/954,987	9/17/01	Bauer et al.
C1041.70019US00	10/140,013	5/6/02	Schetter et al.
C1041.70029US00	10/212,133	8/1/02	Lipford et al.
C1041.70031US00	10/265,072	10/5/02	Lipford
C1041.70035US00	10/373,381	2/24/03	Wagner et al.
C1041.70037US00	10/407,952	4/4/03	Lipford et al.

Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;





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2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;

3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

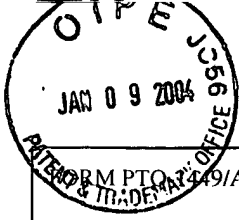
Respectfully submitted,
Arthur M. Krieg, et al., *Applicant*

By: _____

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Date: January 6, 2004
XNDDX





INFORMATION DISCLOSURE STATEMENT BY APPLICANT				APPLICATION NO.: 10/619,279		ATTY. DOCKET NO.: C1039.70077US00	
				FILING DATE: July 14, 2003		CONFIRMATION NO.: 8248	
				APPLICANT: Arthur M. Krieg, et al.			
				GROUP ART UNIT: 1632		EXAMINER: Not yet assigned	
Sheet	1	of	4				

U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	*	5,417,972		Bhat et al.	05/23/1995
	*	5,445,938		Hanai et al.	08/29/1995
	*	5,491,088		Hellstrom et al.	02/13/1996
	*	5,679,647	B1	Carson et al.	10/21/1997
	*	5,756,097		Landucci et al.	05/26/1998
	*	5,780,448	B1	Davis	07/14/1998
	*	5,837,243		Deo et al.	11/17/1998
	**	6,225,292	B1	Raz , et al.	05/01/2001
	*	6,426,334	B1	Agrawal et al.	07/30/2002
	**	6,514,948	B1	Raz, et atl	02/04/2003
	**	6,534,062	B2	Krieg, et al.	03/18/2003
	**	6,552,006	B2	Raz et al.	04/22/2003
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	**	6,610,661	B1	Carson et al.	08/26/2003
	**	6,653,292	B1	Krieg et al.	11/25/2003
	**	US 2001/0046967	A1	Van Nest	11/29/2001
	**	US 2002/0028784	A1	Van Nest	03/07/2002
	**	US 2002/0055477	A1	Nest	05/09/2002
	**	US 2002/0098199	A1	Nest et al.	07/25/2002
	**	US 2002/0107212	A1	Van Nest et al.	08/08/2002
	**	US 2002/0142978	A1	Van Nest et al.	10/03/2002
	**	US 2002/0156033	A1	Raz et al.	10/24/2002
	**	US 2003/0049266	A1	Bratzler et al.	03/13/2003
	**	US 2003/0050263	A1	Fearon et al.	03/13/2003
	**	US 2003/0078223	A1	Krieg et al.	04/24/2003
	**	US 2003/0092663	A1	Raz et al.	05/15/2003
	**	US 2003/0109469	A1	Raz	06/12/2003
	**	US 2003/0119773	A1	Carson et al.	06/26/2003
	**	US 2003/0129251	A1	Raz et al.	07/10/2003
	**	US 2003/0133988	A1	Van Nest et al.	07/17/2003
	**	US 2003/0143213	A1	Fearon et al.	07/31/2003
	**	US 2003/0147870	A1	Raz et al.	08/07/2003
	**	US 2003/0175731	A1	Raz et al.	09/18/2003
	**	US 2003/0186921	A1	Rearon et al	10/02/2003
	**	US 2003/0199466	A1	Fearon et al.	10-23-2003





FORM PTO-1449/A and B (Modified) INFORMATION DISCLOSURE STATEMENT BY APPLICANT				APPLICATION NO.: 10/619,279	ATTY. DOCKET NO.: C1039.70077US00
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Sheet	2	of	4		

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Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	**	US 2003/0212028	A1	Raz et al.	11-13-2003
	**	US 2003/0216340	A1	Van Nest et al.	11-20-2003

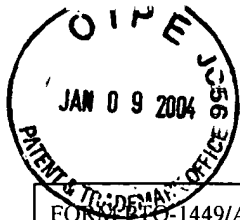
FOREIGN PATENT DOCUMENTS

Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/Country	Number	Kind Code			
	*	WO	96/02560	A1	University of NC at Chapel Hill	02/01/1996	
	B1	WO	99/62923 ✓	A2	Dynavax Tech. Corp	12/09/1999	
	B2	WO	00/20039 ✓	A1	Regents of the University of CA	04/13/2000	
	B3	WO	00/62787 ✓	A1	Regents of the University of CA	10/26/2000	

OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)	
	*	AGGARWAL, S.K. et al., "Cell-Surface-Associated Nucleic Acid in Tumorigenic Cells Made Visible with Platinum-Complexes by Electron Microscopy", <i>Proc. Nat. Acad. Sci. USA</i> , March 1975, Pages 928-932. Vol. 72, No. 3		
	*	BERNHARD, M., et al., "Monocyte Macrophage Mediated Antibody Dependent and Independent Cell Mediated Cytotoxicity in Normals and Cancer Patients, ABSTRACT, Proceedings of AACR and ASCO, 22:372, c-159		
	*	COHEN, J., et al., "IL-12 Deaths: Explanation and a Puzzle", <i>Science</i> , 10:270:5238:908		
	*	COSSUM, P., et al., "Pharmacokinetics of a ¹⁴ C-Labeled Phosphorothioate Oligonucleotide, ISIS 2105, after Intradermal Administration to Rats", <i>The Journal of Pharmacology and Experimental Therapeutics</i> , 269:1:89-94, (1993)		
	*	DOE, B., et al., "Induction of cytotoxic T lymphocytes by intramuscular immunization with plasmid DNA is facilitated by bone marrow-derived cells", <i>Proc. Natl. Acad. Sci.</i> , 93:8578-8583, (1996)		
	*	GATELY, M., et al., "Interleukin-12: A Recently Discovered Cytokine with potential for Enhancing Cell-Mediated Immune Responses to Tumors", <i>Cancer Investigation</i> , 11:4:500-506, (1993)		
	*	HAMBLIN, T., et al., "Ex Vivo Activation and Retransfusion of White Blood Cells", <i>Curr Stud Hematol Blood Transf.</i> , 57:249-266, (1990)		
	*	HARTMANN, G., et al., "CpG DNA: A potent signal for growth, activation, and maturation of human dendritic cells", <i>Proc. Natl. Acad. Sci.</i> , 96:9305-9310, (1999)		
	*	KATAOKA, T., et al. "Immunotherapeutid potential in Guinea-Pig Tumor Model of Deoxyribonucleic Acid From Mycobacterium Bovix BCG Complexed with Poly-L-Lysine and Carboxy-Methylcellulose", <i>Jpn J. Med. Sci. Biol.</i> 43:171-182, (1990)		
	*	KLINMAN, D.M. et al., "Contribution of CpG Motifs to the Immunogenicity of DNA Vaccines", <i>J. of Immunol.</i> , 1997, Pages 3635-3639, Vol. 158, No. 8, The American Association of Immunologists		
	*	KOLITZ, J., et al., "The Immunotherapy of Human Cancer with Interleukin 2: Present Status and Future Directions", <i>Cancer Investigation</i> , 9:5:529-542, (1991)		



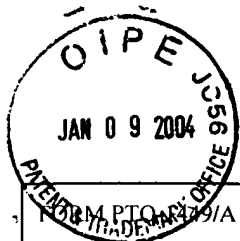


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Sheet	3	of	4

OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	*	KURAMOTO, et al., "In Situ Infiltration of Natural Killer-Like Cell Induced by Intradermal Injection of the Nucleic Acid Fraction from BCG", <i>Microbiol. Immunol.</i> , 33:11:929-940, (1989)	
	*	KURAMOTO, E., et al., "Changes of host cell infiltration into meth a fibrosarcoma tumor during the course of regression induced by injections of a BCG nucleic acid fraction", <i>Int. J. Immunopharmacol.</i> 14:5:773-782, (1992)	
	*	Lacour, J., et al., "Clinical Trials Using Polyadenylic-Polyuridylic Acid as an Adjuvant to Surgery in Treating Different Human Tumors", <i>J of Biological Response Modifiers</i> , 4:538-543, (1985)	
	*	LIPFORD, G.B. et al., "CpG-containing synthetic oligonucleotides promote B and cytotoxic T cell responses to protein antigen: a new class of vaccine adjuvants", <i>Eur. J. Immunol.</i> , 1997, Pages 2340-2344, Vol. 27	
	*	LIPFORD, G.B. et al., "Bacterial DNA as immune cell activator", <i>Inst. of Med. Microb., Immunol. and Hygiene</i> , 1998, Pages 496-500, Elsevier Science	
	*	MASHIBA, H., et al., "In Vitro Augmentation of Natural Killer Activity of Peripheral Blood Cells From Cancer Patients by a DNA Fraction From Mycobacterium Bovis BCG", <i>Jpn J. Med. Sci. Biol.</i> , 41:197-202, (1988)	
	*	MORAHAN, P., et al., "Comparative Analysis of Modulators of Nonspecific Resistance Against Microbial Infections", <i>Immunopharmacology of Infectious Diseases: Vaccine Adjuvants and Modulators of Non-Specific Resistance</i> , 313-324, (1987)	
	*	REISFELD, R., et al., "Monoclonal Antibodies in Cancer Therapy", <i>Clinics in Laboratory Medicine</i> , 12:2:201-216, (1992)	
	*	ROSENBERG, S., et al., "Immunotherapy of Cancer by Systemic Administration of Lymphoid Cells Plus Interleukin-2", <i>Journal of Biological Response Modifiers</i> , 3:501-511, (1984)-	
	*	ROSENBERG, S., et al., "Observations on the systemic administration of autologous lymphokine-activated killer cells and recombinant interleukins-2 to patients with metastatic cancer", <i>The New England Journal of Medicine</i> , 113:23:1485-1492, (1985)	
	*	SHIMADA, S., et al., "In Vivo Augmentation of Natural Killer Cell Activity With A Deoxyribonucleic Acid Fraction of BCG", <i>Jpn J. Cancer Res.</i> , 77:808-816, (1986)	
	*	SHIMADA, S., et al., "Antitumor Activity of the DNA Fraction from Mycobacterium bovis BCG. II> Effects on Various Syngeneic Mouse Tumors", <i>JNCI</i> , 74:3:681-688, (1985)	
	*	STEVENSON, H., et al., "The Treatment of Cancer with Activated Cytotoxic Leukocyte Subsets", <i>Artif Organs</i> , 12:2:128136, 1988	
	*	STULL, R.A. et al., "Antigene, Ribozyme and Aptamer Nucleic Acid Drugs: Progress and Prospects", <i>Pharmaceutical Research</i> , 1995, Pages 465-483, Vol. 12, No. 4, Plenum Publishing Corp.	
	*	SUN, S. et al., "Mitogenicity of DNA from Different Organisms for Murine B Cells", <i>The Journal of Immunology</i> , 1997, Pages 3119-3125, The American Association of Immunologists	
	*	THREADGILL, D.S. et al., "Mitogenic synthetic polynucleotides suppress the antibody response to a bacterial polysaccharide", <i>Vaccine</i> , 1998, Pages 76-82, Vol. 16, No. 1, Elsevier Science Ltd.	
	*	TOPALIAN, S., et al., "Expansion of human tumor infiltrating lymphocytes for use in immunotherapy trials", <i>J of Immunological Methods</i> , 102:127-141, (1987)	
	*	TORPEY III, D., et al., "Effects of Adoptive Immunotherapy with Autologous CD8+ t Lymphocytes on Immunologic Parameters: Lymphocyte Subsets and Cytotoxic Activity", <i>Clinical Immunology and Immunopathology</i> , 68:3:263-272, (1993)	
	*	VOGELS, M., et al., "Use of Immune Modulators in nonspecific Therapy of Bacterial Infections", <i>Antimicrobial Agents and Chemotherapy</i> , 36:1:1-5, (1992)	





INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICATION NO.: 10/619,279	ATTY. DOCKET NO.: C1039.70077US00
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Sheet	4	of	4

OTHER ART — NON PATENT LITERATURE DOCUMENTS

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	*	WILTROUT, R.H., et al., "Immunomodulation of Natural Killer Activity by Polyribonucleotides", <i>Journal of Biological Response Modifiers</i> , 1985, Pages 512-517, Vol. 4, No. 5, New Raven Press, NY	
	*	WOOLDRIDGE, J., et al., "Immunostimulatory Oligodeoxynucleotides Containing CpG Motifs Enhance the Efficacy of Monoclonal Antibody Therapy of Lymphoma", <i>Blood</i> , 89:8:2994-2998, (1997)	
	*	WOOLDRIDGE, J.E. et al., "Select Unmethylated CpG Oligodeoxynucleotides Improve Antibody Dependent Cellular Cytotoxicity <i>in Vitro</i> of Both Murine and Human B Cell Lymphomas", <i>Blood</i> , December 1995, Page 2877, Abstract, Vol. 86	
	*	WOOLDRIDGE, J.E. et al., "Select unmethylated CpG oligodeoxynucleotide improve antibody dependent cellular cytotoxicity <i>in vitro</i> and <i>in vivo</i> ", Proceedings of the American Association for Cancer Research #3253, March 1996, Page 477, Abstract, Vol. 37	

EXAMINER	DATE CONSIDERED
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#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

*a copy of this reference is not provided as it was previously cited by or submitted to the office in one of the prior applications, Serial No. 08/386,063, filed February 7, 1995, Serial No. 08/738,652, filed October 30, 1996, Serial No. 09/337,619, filed June 21, 1999, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

** copies of these patents and patent applications are not enclosed pursuant to the waiver by the USPTO of the requirement under 37 C.F.R. 1.98 (a)(2)(i) for patent applications filed after June 30, 2003.

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